

DuPont Haskell Laboratory
for Toxicology and Industrial Medicine
Elkton Road, P. O. Box 50
Newark, DE 19714-0050



DuPont Haskell Laboratory

Gerald L. Kennedy
Director, Applied Toxicology
DuPont Haskell Laboratory
P.O. Box 50
Elkton Road
Newark, Delaware 19714-0050
Phone: (302) 366-5259

VIA FEDERAL EXPRESS

Document Control Office (7407)
Room G99 East Tower ATTN: FYI
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

March 8, 2001

Dear Sir/Madam: *

FYI-0101-001378

This letter is in reply to Richard H. Hefter's letter dated February 14, 2001 to me concerning the above-referenced FYI submission.

The information provided in the January 25, 2001 and June 23, 2000 submissions was provided voluntarily to EPA in response to a request from Mr. Charles Auer for exposure and use information from DuPont pertaining to the substance in issue. The blood serum test results reflect exposure data. No adverse health effects associated with this substance have been found among exposed employees. It is further noted that studies submitted by the 3M Company, which is the manufacturer of the substance, also conclude that no health effects associated with this substance have been found amongst its exposed employees (see 3M SEHQ-0200-14596, dated January 28, 2000). Those studies, either themselves or through reference to other studies published in the open scientific literature, report that this substance is known to be found in human blood serum of employees exposed to the substance¹.

¹ See (a) Gilliland FD, Mandel JS. Mortality Among Employees of a Perfluorooctanoic Acid Production Plant. J. Occup. Med. 1993;35:950-954; (b) Gilliland FD, Mandel JS. Serum Perfluorooctanoic Acid and

GK003126

04/03/01 09:05:20 02/03 NO:255

828 151 205 302 451 4828

DUPONT HASKELL LAB

GK003126

Per EPA's June 1991 TSCA Section 8(e) Reporting Guide, it is provided that "In deciding whether information is 'substantial risk' information, one must consider 1) the seriousness of the adverse effect, and 2) the fact or probability of the effect's occurrence." As stated above, no adverse health effects associated with this substance have been found among exposed employees. In the absence of an adverse effect, the information was deemed to not meet EPA TSCA Section 8(e) reporting criteria.

In addition, per the 1991 TSCA Section 8(e) Reporting Guide, information need not be submitted if it is published in the open scientific literature. As referenced above, prior published studies have reported that this substance is present in the blood serum of workers exposed to the substance. Also, in 1980, it was reported in the American Industrial Hygiene Association Journal that perfluorooctanoate anion was found in the blood of workers exposed to ammonium perfluorooctanoate¹. The blood serum information provided in the DuPont submissions is not indicative of information not known to the Agency. It is consistent with information already published in the open scientific literature and as such, was deemed to not meet the criteria for TSCA section 8(e) reporting.

Please contact me directly if you need further clarification or wish to discuss this matter in more detail.

Very truly yours,


Gerald Kennedy

Hepatic Enzymes, Lipoproteins, and Cholesterol: A Study of Occupationally Exposed Men. Am. J. Ind. Med. 1996;29:560-568; (c) Olsen GW, Gilliland PD, Burlew MM, Burris JM, Mandel JS, Mandel JH. An Epidemiologic Investigation of Reproductive Hormones in Men with Occupational Exposure to Perfluorooctanoic Acid. J. Occup. Env. Med. 1998;40:614-622.

¹ Ubel FA, Sorenson SD, Rouch, DE. Health Status of Plant Workers Exposed to Fluorochemicals - a Preliminary Report. American Industrial Hygiene Association Journal. 1980;41:584-589.

GK003127